



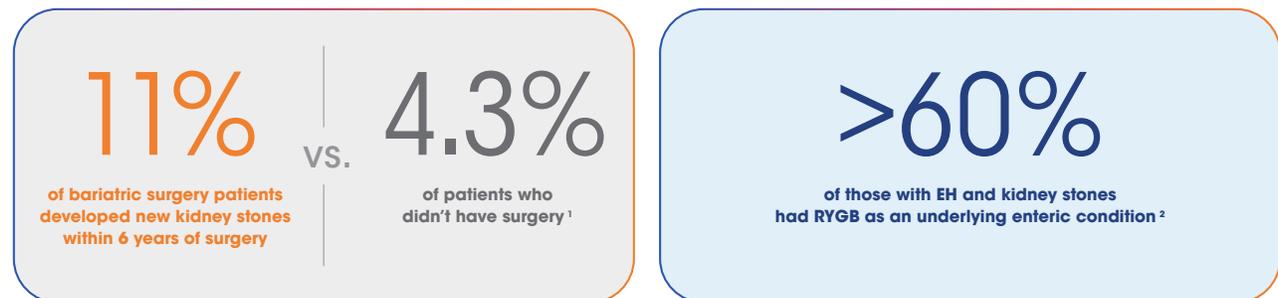
The SYNHOX Study

Advancing research in kidney health for bariatric surgery patients

People who have undergone Roux-en-Y gastric bypass (RYGB) surgery have faced many ups and downs in their health journey. One unintended consequence of complications from RYGB is enteric hyperoxaluria (EH).

RYGB has been the principal bariatric surgery associated with significantly higher urinary calcium oxalate supersaturation (CaOxSS), which contributes to developing calcium oxalate stones. EH increases the risk of kidney stones and, in more severe cases, chronic kidney disease, which could even lead to kidney failure.

There are no approved therapies for EH.



The SYNHOX Study

- Phase: 1b
- Design: Double-blind, randomized, placebo-controlled; 2 dosing periods with crossover
- Duration: 6 months, with 2 study treatment periods that are up to 10 days each
- Investigational drug: SYN8802 oral biologic at 3×10^{11} live cells, orally, up to 3 times per day (TID) or per dose-ramp schedule, with meals
- Study Population: N=20 with EH, >1 year post RYGB surgery
- Remote Option: Study visits may be completed at a study location or, if preferred, at a remote location, such as the participant's home with a home health professional

Primary Inclusion / Exclusion Criteria

INCLUSION	EXCLUSION
Age ≥ 18 to ≤ 74 years	Acute renal failure or estimated glomerular filtration rate <45 mL/min/1.73 m ²
Enteric hyperoxaluria secondary to Roux-en-Y bariatric surgery (at least 12 months post-surgery)	Diagnosis of primary hyperoxaluria or any other cause of hyperoxaluria
Urinary oxalate ≥ 50 mg/24 hours (mean of at least 2 urine collections during Screening or within 90 days of the scheduled first dose of IMP)	Currently taking or plans to take any type of systemic (e.g., oral or intravenous) antibiotic within 30 days prior to Day 1 through the final safety assessment. Exception: Topical antibiotics are allowed.

For more information, or to refer a patient, go to kidneyhealthstudy.com.



Scan this code for more information.

¹ Lieske JC, Mehta RA, Milliner DS, Rule AD, Bergstralh EJ, Sarr MG. Kidney stones are common after bariatric surgery. *Kidney International*. 2014;87(4):839-845. doi:10.1038/ki.2014.352

² Tasian G, Wade B, Gaebler J, Kausz A, Medicis J, Wyatt C. Prevalence of kidney stones in patients with enteric disorders. Paper presented at American Society of Nephrology Washington, DC, 2019.